User Manual

Newtron handpiece

ACTEON

This document is an English translation of the original French version.
Reference J12640 version V7 and drawing number NG62FR070G

Contents

1 Documentation

This document contains the following information:

- Indications for use
- Medical device description
- Installation of the medical device
- Medical device use
- Preparation for cleaning and disinfection of the medical device
- Monitoring and general maintenance of the medical device
- Maintenance to be performed by the user

1.1 Associated documentation

This document must be used in association with the following documents:

Document title	References
Consulting electronic user instructions	J00007
General instructions relating to the complete range of dental ultrasonic generators	J00011
Cleaning, disinfection and sterilisation instructions for handpieces	J12911
Cleaning, disinfection and sterilisation instructions for keys	J81001
Cleaning, disinfection and sterilisation instructions for tips	J02001
Newtron handpiece user manual	J12641
Newtron handpiece Quick Start-Clean guide	J12280

> The Quick Start and Quick Clean documents are summaries created for your approval. The only binding instructions are the user manuals and regulatory documentation associated with the medical device.

1.2 Electronic documentation

The user instructions for your device are available in electronic format on the specified website and not in printed format. If the website is unavailable, try again later. You can also request a free printed copy of the user instructions within seven days via our website, by telephone or in writing.
The electronic user instructions are available in PDF format (Portable Document Format). You will need to have a PDF file reader installed to read the electronic user instructions. It is important for you to have read and understood the content of the user instructions relating to the use of your device and its accessories.

> Never use your device without first reading the user instructions.

The device user instructions can be consulted at `www.satelec.com/documents`
When you receive your device, you are asked to print and/or to download all documents or sections of documents that you may need to refer to in the event of an emergency, if you are unable to connect to the internet or if your electronic display tool is not working (computer, tablet, etc.). We recommend that you visit the website regularly to consult and to download the latest version of your device's user instructions. Users are asked to keep documentation close at hand for reference when necessary.

2 Required information

2.1 Indication for use

The dental ultrasonic handpiece is used in association with a conventional dental piezoelectric ultrasonic generator and a tip or a dental file.
The treatments performed with this medical device are those described in the User Manual for your ultrasonic generator.

2.2 Operating principle

This handpiece works on piezoelectric ultrasonic generators fitted with a Newtron connector.
An electrical signal emitted by the medical device is supplied to the ultrasonic handpiece. This is connected to the medical device via a cord. The handpiece comprises a piezoelectric ceramic transducer, which transforms the electrical signal into ultrasonic vibrations.

2.3 Using accessories not supplied by the manufacturer

The handpiece is designed to operate with SATELEC, a company of Acteon group dental tips and files. The use of tips or files made by other manufacturers will damage the handpiece, break tips and files and void the warranty.

2.4 Connecting and disconnecting accessories during use

Do not tighten or loosen the tips when the handpiece is activated.

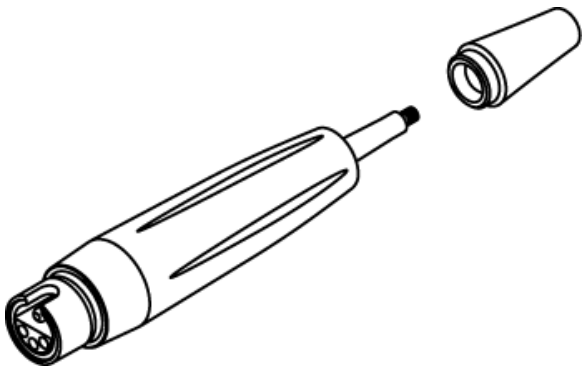
2.5 Repairing or modifying the medical device

Contact the supplier of your device. Using the services of an unapproved repairer could render your device dangerous for you and your patients.
Do not repair or modify the device without seeking the prior permission of SATELEC, a company of Acteon group.
If the device is modified or repaired, specific checks and tests must be carried out to ensure that the medical device is still safe to use.
In the event of doubt, contact an approved dealer or the SATELEC, a company of Acteon group Customer Service team:
`www.acteongroup.com`
`satelec@acteongroup.com`

> SATELEC, a company of Acteon group, at the request of technical personnel working for the network of approved dealers, will provide any information required to repair defective parts on which they may perform repairs.

2.6 Warranty

Only clearly indicated parts of the medical device can be unscrewed by the user. Unscrewing any other parts may void the warranty.



2.7 Latest document update

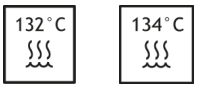
02/2023

2.8 Date of first CE marking

2003

2.9 Accessory usage conditions

The accessories and the handpiece must be cleaned, disinfected and sterilised prior to each use.


132°C
134°C

3 Unpacking the medical device

When you receive your medical device, check for any damage that may have occurred during transportation.
If you have received this medical device by mistake, please contact the supplier to arrange for it to be collected.
If you have any questions or requirements, contact your supplier.
The Newtron handpiece includes the following items:

- a Newtron handpiece;
- a Quick Start- Clean guide for the handpiece Newtron [J12280].

4 Installing the medical device

4.1 Handpiece

The handpieces are designed to operate exclusively with SATELEC dental ultrasonic generators.

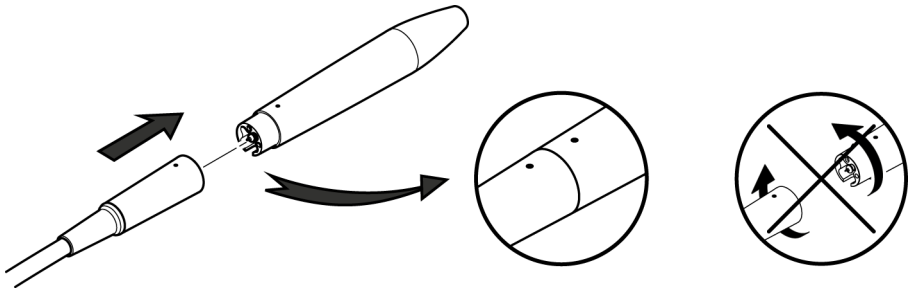
4.2 Handpiece cord

The cord ensures irrigation circulation and electrical connection between the medical device and the handpiece.
Never rotate the handpiece connector on its cord as this can damage your medical device.
Never wrap the handpiece cord around the medical device.
Make sure that it is not possible to wheel over or walk on the different cords.
The cord attached to its handpiece must be easily accessible. Make sure that the cord is slack during use.

4.3 Connecting the handpiece

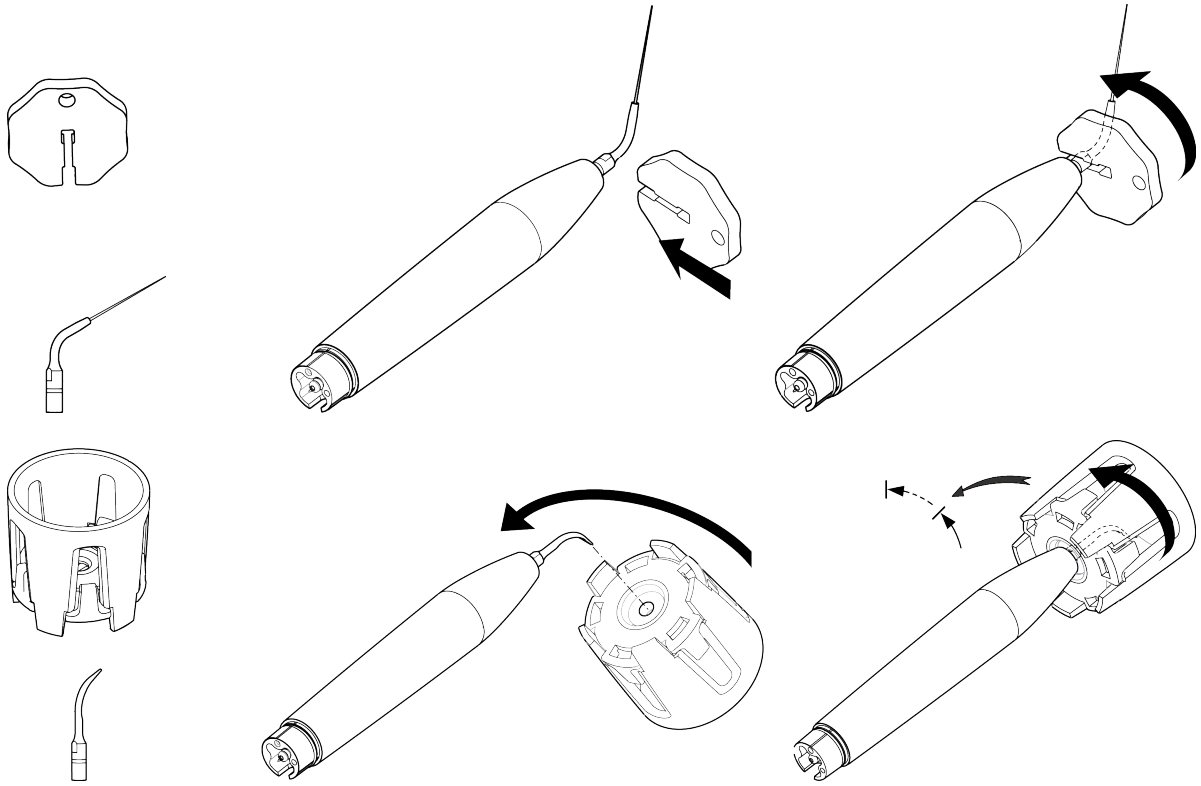
Check for any traces of humidity on the handpiece connections. If the connections are damp, dry them with the multi-purpose syringe.

> Lubricate the irrigation circuit seal located on the metal shaft on the back of the handpiece with silicone paste. This will prolong its service life and prevent leaks. Do not use spray lubricant on dental instruments.



Place the handpiece on the support.
A tip or a file vibrates correctly when it is perfectly tightened without being forced beyond its stop point. Tighten the tip with the torque wrench (F81320, F81321, F81322 or F81323) to ensure optimum ultrasonic function. Over-tightening of the tip or file with the open-ended wrench can result in breakage of the tip, file or handpiece.

> To prevent self-locking of the tip or the file, the latter must be removed and sterilised after each use.



The torque wrenches must be replaced every year.

5 Dispensing a treatment

5.1 Accessory usage conditions

The accessories and the handpiece must be cleaned, disinfected and sterilised prior to each use.

Refer to the cleaning, disinfection and sterilisation instructions for accessories listed in the chapter *Associated documentation page 3*.

5.2 Preparation for use


To prepare your medical device, follow the steps below:

1. Wear safety goggles and protective gloves.
2. Clean the unit with an alcohol disinfectant wipe.
3. Remove the handpiece from its sterilisation bag.
4. Remove the wrench from its sterilisation bag.
5. Remove the tip from its sterilisation bag.
6. Screw the tip onto the handpiece, first manually and finishing with the wrench.
7. Connect the handpiece to the handpiece cord socket.
8. Place the handpiece on its support.
9. Switch on the medical device.
10. Check the irrigation parameters depending on the tip chosen.
11. After water drainage, check that the spray works correctly.

Your medical device is now ready to use.

6 Disinfection and sterilising

The instructions relating to cleaning, disinfection and sterilisation protocols for accessories provided by SATELEC, a company of Acteon group have been approved for each medical device and accessory. The applicable guides are listed in the chapter *Associated documentation page 3*.
They can be downloaded at the following address: `www.satelec.com/documents`.

Download

Instructions For Use

In all cases, the local regulations in force relating to the cleaning, disinfection and sterilisation protocols for accessories take precedence over the information provided by SATELEC, a company of Acteon group.

6.1 Clean and disinfect the medical device

The medical device's control unit must be cleaned and disinfected daily.
The handpiece must be cleaned, disinfected and sterilised after each use.

> Do not immerse the handpiece.

The medical device must be in OFF or O stop position during cleaning and disinfecting procedures.
Refer to the instructions in the chapter *Cleaning the irrigation system page 15*.
Use alcohol disinfectant wipes.
Avoid using cleaning and disinfection products that contain flammable agents.
Otherwise, ensure that the product has completely evaporated or that there is no fuel left on the medical device and its accessories before switching it on.

> Do not use an abrasive product to clean the medical device.

> Never apply sprays directly to the medical device to clean it. Always spray the product onto a wipe, then clean the medical device.

6.2 Cleaning, disinfecting and sterilising accessories

Refer to the cleaning, disinfection and sterilisation instructions for accessories listed in the chapter *Associated documentation page 3*.

7 Monitoring and routine maintenance

Check the cleanliness of the handpiece nosepiece. It must be clean, smooth and corrosion-free. The handpiece must screw easily and firmly inside it.
Check the condition of the handpiece rear seals, which must not be distended, torn or broken.
Before and after use, check the medical device and its accessories entirely for any problems. This is necessary to detect any electrical isolation fault or damage. If necessary, replace damaged parts.

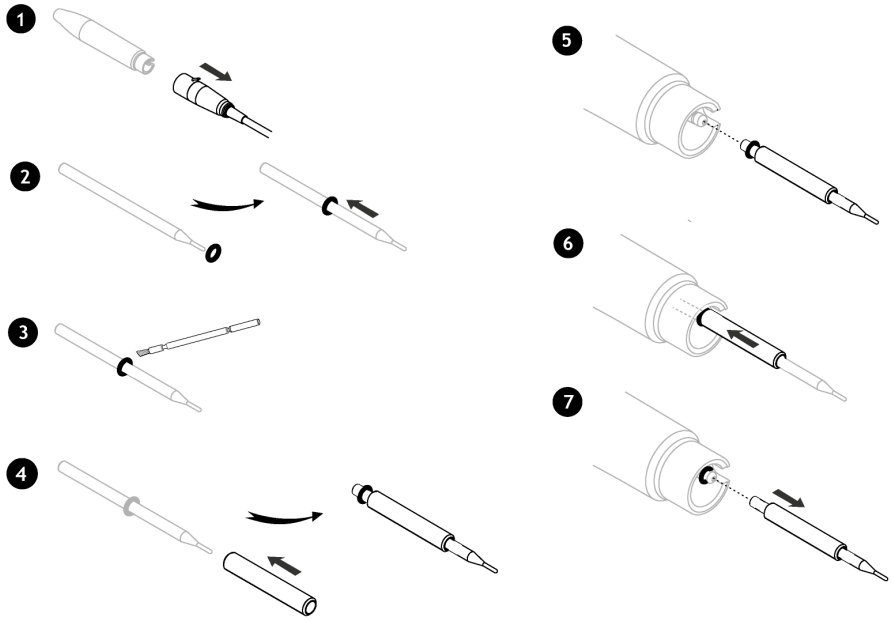
7.1 Cleaning the irrigation system

After installation and before first use, at the end of the day and following a period of prolonged non-use of the medical device, it is important to clean the irrigation system.
Operate the device at minimum power, at maximum irrigation flow rate for two minutes.

7.2 Corrective Maintenance

7.2.1 Replacing the handpiece seal

Remove the faulty seal from the water connector using a thin pair of pliers.
Install the new seal using the purpose-designed kit as shown below.



8 Identifying incorrect operation

In the event of incorrect operation, refer to the tables below to quickly identify and repair the non-complex parts of the medical device.
If the incorrect operation is not described in the tables below, please contact your supplier or the customer service team at SATELEC, a company of Acteon group.
Do not use the medical device if it appears to be damaged or faulty. Isolate the medical device and make sure that it cannot be used.

8.1 No spray

Symptom: There is no water spray at the tip.

Possible causes	Solutions
Tip or file blocked	Unblock the tip or file using an ultrasonic tank
Incorrect choice of tip	Check the tip
Inadequate amount of spray	Adjust the spray

> Do not ever try to unblock a tip or file using a probe.

8.2 Ultrasounds not working

Symptoms: the tip does not vibrate.

Possible causes	Solutions
The tip is incorrectly tightened	Fasten the tip using the wrench Replace your torque wrench once a year
Faulty connector contact	Clean the cord contacts
Handpiece cord wire(s) cut	Return to the Acteon Customer Service team to replace the cord

8.3 Water leakage

Symptoms: water is leaking between the base of the handpiece and its cord.

Possible causes	Solutions
Wear of 1.15 mm x 1 mm handpiece seal	Replace the seal using the purpose-designed kit.

9 Technical specifications of the medical device

9.1 Identification

Manufacturer	SATELEC, a company of Acteon group
Name of the medical device	Newtron handpiece

9.2 Handpiece

Length	113 mm
Diameter maximum	21 mm
Weight	55 g

9.3 Length of cords

Handpiece cord	2 000 mm +/- 50 mm

9.4 Irrigation

Water pressure at inlet	from 1 to 5 bars (15 to 73 p.s.i.)
Water output at the end of the handpiece	0 ml/min to 80 ml/min at 5 input bar

9.5 Environmental characteristics

Ambient operating temperature	+10°C to +30°C
Operating RH	30% to 75%
Atmospheric operating pressure	Between 800 hPa and 1060 hPa
Maximum operating altitude	Equal to or less than 2000 metres
Storage temperature	-20°C to +70°C
Storage RH	10% to 100%, including condensation
Atmospheric storage pressure	Between 500 hPa and 1060 hPa
Transportation temperature	-20°C to +70°C
Transportation RH	10% to 100%, including condensation
Atmospheric transportation pressure	Between 500 hPa and 1060 hPa

9.6 Environmental restrictions

Usage premises	Usable in all medical premises. The medical device must not be used in an operating theatre or outdoors.
Use in gas-filled atmosphere	The medical device is not designed for use in a type AP or APG gas-filled atmosphere or in the presence of anaesthetic gases.
Immersion	The handpiece must not be immersed.

9.7 Main performance characteristics

Ultrasonic vibrations of the tip or file fitted to the end of the conventional dental ultrasonic handpiece.

- Vibration frequency ≥ 28 kHz.
- Tip amplitude ≤ 200 µm.

10 Regulations and standards

10.1 Applicable standards and regulations

This medical device complies with the essential requirements of European Directive 93/42/EEC. It was designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system.
This equipment is designed and developed in compliance with the Electrical Safety standard IEC60601-1 in force.

10.2 Medical class of the device

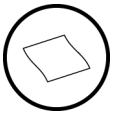
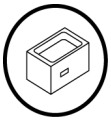
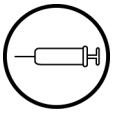
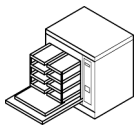
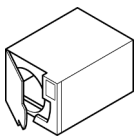
Class of medical device: IIa according to 93/42/EEC directive

10.3 Symbols

Symbol	Meaning
	Always wear safety goggles
	Always wear protective gloves
	Refer to the supporting documentation
	Consult the User Manual
	The accompanying documentation is available in electronic format
	Pressure limit
	Temperature limit
	Humidity limit
	Packaging unit

Symbol	Meaning
	Fragile, handle with care
	Store in a dry place
	Sterilise prior to each use
	Biohazard
	Sterilisation at 134°C in an autoclave
	Sterilisation at 132°C in an autoclave
	Washer-disinfector for thermal disinfection
	CE marking
	CE marking
YYYY 	Year of manufacture
	Manufacturer
	Do not dispose of as household waste
	Recycle your lamps and professional electrical equipment with Récylum
Rx Only	Under the United States Federal Law, this medical device must only be sold by or under the orders of a qualified doctor.
SN	Serial Number
PN	Packaging Number

10.4 Quick Start and Quick Clean symbols

	Use a soft brush for cleaning
	Use a lint-free cloth for cleaning
	Use an ultrasonic tank for cleaning.
	Use a swab for cleaning
	Use an alcohol disinfectant wipe for pre-disinfection and cleaning.
	Do not use the ultrasonic tank for cleaning.
	Clean under running water
	Use a syringe for cleaning
	Use a washer-disinfector for cleaning and disinfection
	Use a pre-vacuum air autoclave for sterilisation

10.5 Manufacturer identification

SATELEC
A Company of the ACTEON Group
17, avenue Gustave Eiffel
BP 30216
33708 MERIGNAC cedex
France
Tel. +33 (0) 556.34.06.07
Fax. +33 (0) 556.34.92.92
E-mail: satelec@acteongroup.com
www.acteongroup.com

CE Marking 0459

10.6 Branch addresses

AUSTRALIA/NEW ZEALAND
ACTEON AUSTRALIA/NEW ZEALAND
Suite 119, 30-40 Harcourt Parade
Rosebery NSW 2018
Australia
Tel. +612 9669 477 307
Fax. +612/96692204
info.au@acteongroup.com

BRAZIL
MICRO IMAGEM INDUSTRIA COMERCIO IMPORTAÇÃO E EXPORTAÇÃO LTDA
CNPJ: 14.041.012/0001-79
Alameda Vênus, 233
Distrito Industrial
Indaiatuba – SP – CEP 13347-659
Brazil
Tel. +55 19 3936 809

CHINA
ACTEON CHINA
Office 401 - 12 Xinyuanxili Zhong Street -
Chaoyang District - BEIJING 100027 - CHINA
Tel. +86 10 646 570 11/2/3
Fax. +86 10 646 580 15
info.cn@acteongroup.com

GERMANY
ACTEON GERMANY GmbH
Industriestrasse 9 – 40822 METTMANN - GERMANY
Tel. +49 21 04 95 65 10
Fax. +49 21 04 95 65 11
info.de@acteongroup.com

Hong Kong Re. Office
21/F, On Hing Building
Central - Hong Kong
Tel. +852 66 962 134
info.hk@acteongroup.com

MIDDLE EAST
ACTEON MIDDLE EAST
247 Wasfi Al Tal str.
401 AMMAN - JORDAN
Tel. +962 6 553 4401
Fax. +962 6 553 7833
info.me@acteongroup.com

RUSSIA
ACTEON RUSSIA
Moscow, Gilyarovskogo str, 6b1
+7 495 1501323
info.ru@acteongroup.com

SPAIN
ACTEON MEDICO-DENTAL IBERICA, S.A.U.
Avda Principal n°11 H
Poligono Industrial Can Clapers
08181 SENTMENAT (BARCELONA) - SPAIN
Tel. +34 93,715 45 20
Fax. +34 93,715 32 29
info.es@acteongroup.com

TAIWAN
ACTEON TAIWAN
11F., No.1, Songzhi Rd.
Xinyi Dist., Taipei City 11047
TAIWAN (R.O.C.)
+ 886 2 8729 2103
info.tw@acteongroup.com

THAILAND
ACTEON (THAILAND) LTD
23/45 Sorachai Building 16th floor - Sukumvit 63 Road, Klongton Nua - Wattana, BANGKOK 10110 - THAILAND
Tel. +66 2 714 3295
Fax. +66 2 714 3296
info.th@acteongroup.com

INDIA
ACTEON INDIA
1202, PLOT NO. D-9
GOPAL HEIGHTS, NETAJI SUBASH PLACE
PITAMPURA, DELHI - 110034 - INDIA
Tel. +91 11 47 018 291 / 47 058 291 / 45 618 291
Fax. +91 79 2328 7480
info.in@acteongroup.com

LATIN AMERICA
ACTEON LATINA AMERICA
Bogotà - COLOMBIA
Mobile: +57 312 377 8209
info.latam@acteongroup.com

U.K.
ACTEON UK
Phoenix Park– Eaton Socon, St Neots
CAMBS PE19 8EP - UK
Tel. +44 1480 477 307
Fax. +44 1480 477 381
info.uk@acteongroup.com

U.S.A. & Canada
ACTEON North America
124 Gaither Drive, Suite 140
Mount Laurel, NJ 08054 - USA
Tel. +1 856 222 9988
Fax. +1 856 222 4726
info.us@acteongroup.com

10.7 Disposal and recycling

As an item of Electrical and Electronic Equipment, the medical device must be disposed of via a specialist collection, removal, recycling or destruction channel. This applies in particular to the European market, with reference to Directive no. 2012/19/EC of July 2012.

When your medical device has reached the end of its service life, contact your nearest dental equipment dealer, or the Acteon head office or one of the company branches to find out how to proceed. The relevant contact details are given in the chapter *Branch addresses page 24*.

Do not dispose of as household waste

The indication below applies to France only.

In compliance with the provisions of the French Environment Code relating to the disposal of electronic and electrical equipment waste or WEEE (Decree no. 2012-617 dated 2 May 2012), our Company fulfils its obligations to reclaim and dispose of its electrical and electronic equipment through the means established by the approved organisation Récylum, NOR approval: DEVP1427651A.

As a manufacturer, our Company is listed in the National Register of Producers kept by the ADEME (French Environment and Energy Management Agency). Professionals buying our products directly from the distribution chain are responsible for passing on this information about our established recycling methods to the end user.

In addition, the buyer agrees to take back our brand's devices at the end of their service life and to transfer them to one of the collection centres set up by Récylum for recycling (see list of collection centres on the site `http://www.recylum.com/`).

If necessary, Récylum can come and collect these devices from you free of charge once the quantity of devices has reached a certain level in the pallets-containers with which you are provided to store this waste.

An accessory that has reached the end of its service life must be disposed of in infectious clinical waste containers.

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CE 0459
CE Marking

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SATELEC S.A.S. | A Company of the ACTEON Group
17 av. Gustave Eiffel | BP 30216 | 33708 MERIGNAC cedex | FRANCE
Tel. +33 (0) 556 34 06 07 | Fax. +33 (0) 556 34 92 92
Email: satelec@acteongroup.com | www.acteongroup.com

ACTEON